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K003046

510K Summary Statement for the Sciton Inc Image Hair Removal Laser

1. General Information

Submitter:	Sciton Inc 845 Commercial Street Palo Alto, CA 94303
Contact Person	Peter Allen
Summary Preparation Date	June 6, 2000

2. Names

Device Names	Image, Image Vascular Laser and Image Long Pulse Nd:YAG
Primary Classification Names:	Laser Powered Surgical Instrument for use in Plastic Surgery and Dermatolgy in accordance with 21CFR 879-4810.79-GEX

3. Predicated Devices

The product specifications, functionality, indications for use, and treatment parameters of the Sciton Inc Vascular Laser are the same or very same to the following legally market lasers:

Altus Medical, Nd:YAG Aesthetic Laser

Laserscope, Long Pulse Nd:YAG

HGM VeinLase

ESC VascuLight

4. Product Description

The Sciton Inc, Vascular Laser is a long pulsed, solid state infrared laser. It is intended to deliver laser energy for use in surgical and aesthetic applications requiring the coagulation of vascular lesions. The Vascular Laser produces a beam of infrared light at a wavelength of 1064nm. The system consists of:

A laser console
Internal computer
Control panel and display
Articulated Arm
Footswitch with optional handswitch
Handpieces with cooling capability

5. Indications for Use

The Sciton Inc Image Vascular Laser is intended for use in surgical, and aesthetic applications for the treatment of vascular lesions in general, plastic surgery and dermatology on Fitzpatrick skin types I-VI.

6. Rationale for Substantial Equivalence

The Sciton Inc Vascular Laser shares the same indications for use, similar design features (including wavelength, active medium, cooling system and controls), similar functional features (including pulse duration and fluence), and similar treatment parameters of other marketed long pulse Nd:YAG laser systems (as opposed to Q-switched lasers). Therfore the Sciton Inc Vascular Laser is substantially equivalent to the Altus Medical Laser Nd:YAG Aesthetic Laser, Laserscope, HGM and ESC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Peter Allen
Director, Regulatory Affairs
Sciton, Inc.
845 Commercial Avenue
Palo Alto, California 94303

MAY 1 5 2001

Re: K003046
Trade/Device Name: Image Vascular Laser System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: September 28, 2000
Received: September 29, 2000

Dear Mr. Allen:

This letter corrects our substantially equivalent letter of November 24, 2000, regarding the address.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA Submission Cover Sheet

510(K) Number (if known): K003046

Device Name: Sciton Image Hair Removal Laser

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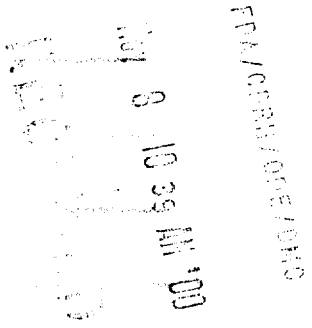

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __✓__ OR Over The Counter Use _____
(Per 21CFR 801)

for Mark N. Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003046